REMARKS

Claims 72, 74-79, 81-83, 85, 92, 96-99, 101-103, 105, 107, and 113-116 are pending in the application. No claim amendments are presented at this time. The specification has been amended to capitalize trademarks. This amendment of the specification does not add new matter. Applicants courteously acknowledge the withdrawal of all rejections under 35 U.S.C. §§ 101, 102(b), and 112, and under the doctrine of obviousness-type double patenting, as well as some rejections under 35 U.S.C. § 103(a). Applicants also thank the Examiner for the helpful interview with the undersigned on January 13, 2009.

Rejections Under 35 U.S.C. § 103

In the last Office Action, the Examiner maintained the rejection of claims 72, 74, 75, 81-83, 85, 96-99, 101-103, 105, 107, and 113-116 under 35 U.S.C. § 103(a) over Kim et al. (WO 01/28602) in view of Vercruysse et al., *Critical Review in Therapeutic Drug Carrier Systems* 15:513-55 (1998) and Campoccia et al., *Biomaterials* 19: 2101-27 (1998) and further in view of Shalaby et al. (U.S. Patent No. 6,221,958) and Daifotis et al. (U.S. Patent No. 6,015,801).

Applicants respectfully request withdrawal of this rejection for at least the following reasons.

The primary reference cited by the Examiner does not teach or suggest all the limitations of the claims and the supporting references do not remedy this deficiency. Applicants' claims require that the composition be "a solid cylindrical rod suitable for intraosseous injection in solid state." The primary reference of Kim does not teach a composition "suitable for intraosseous injection in solid state." Rather, Kim discloses, for example, "porous injectable gels and pastes." Kim at Abstract. Whenever the

compositions of Kim are described, they are referred to as "injectable gel or paste formulations." Gels and pastes are not solid. Therefore, Kim does not disclose a composition meeting the required limitation that the composition be "suitable for intraosseous injection in solid state," because solidity at the time of injection is lacking in the Kim compositions.

Furthermore, Kim fails to teach compositions that do not contain pore formers or pores. The instant claims are directed to solid, i.e., nonporous, cylindrical rods. Kim teaches that the hyaluronic acid esters must have pores, thereby teaching away from the use of solid compositions for similar methods. Kim teaches numerous advantages of this porosity: "[t]he amount, type, and size of the pore forming agent is optimized to leave voids sufficient for cell ingrowth into injectable gel when pore forming agent and solvent are extracted from the carrier in vivo by solubilization of pore forming agent and precipitation/phase inversion of carrier in situ." Kim at Col. 2-3 ll. 66-4. From the language of this passage, one of ordinary skill in the art at the time of Applicants' invention would understand that formation of voids for cell ingrowth was clearly desirable. This constitutes teaching away from a lack of such voids, and a solid structure must not contain voids.

Regardless of the alleged teachings of the secondary references (Vercruysse, Campoccia, and Shalaby), they certainly do not describe to one of ordinary skill in the art that a composition "suitable for intraosseous injection in solid state" would be effective. That is, the teaching of Kim quoted above cannot allow for a reasonable expectation of success and nothing in the secondary references teaches or suggests that solid rods as claimed by Applicants would be effective for treatment of bone defects

or other uses of Applicants' compositions. Indeed, Shalaby, the reference which the Examiner alleges to disclose formation of cylindrical rods (Office Action at 8-9), does not recite anything concerned with bone treatment.

Solidity is not merely a design choice for a composition whose form is not relevant to its function. Rather, the solid rod nature required by Applicants' claims confers an advantage in that solid rods are less likely to give rise to embolism. Embolism is always a risk when delivering the liquids or pastes. The liquid or paste can quickly leave the delivery device and expand into the body in a harmful manner. The solid rods of the invention overcome this risk by delivering the same amount of material in a much smaller volume. Furthermore, the cylindrical solid shape prevents embolism because it is less likely to break up immediately after delivery.

Claims 101 to 103 recite compositions comprising a bone resorption inhibitor; claims 102 to 103 specify that the inhibitor is a bisphosphonate. In rejecting these claims, the Examiner alleges that Daifotis discloses that bisphosphonates are poorly absorbed from the gastrointestinal tract, that intravenous administration is costly and inconvenient, and that oral administration has been associated with adverse gastrointestinal effects. The Examiner then concludes that this reference combined with the others renders it obvious to add alendronate (a bisphosphonate) to the claimed compositions. Applicant respectfully submit that Daifotis does not contain a teaching or suggestion to add alendronate to a composition suitable for intraosseous injection, and that therefore rejection of claims 101 to 103 under 35 U.S.C. § 103(a) is inappropriate for this additional reason.

Applicants respectfully submit that the rejection under 35 U.S.C. § 103(a) is erroneous for at least the foregoing reasons and courteously request withdrawal of the rejection and timely allowance of the claims.

Objection to trademarks and their use

The Examiner objected to the use of trademarks in this application. Specifically, the Examiner stated, "The trademarks have not been capitalized, they should be capitalized wherever they appear and be accompanied by the generic terminology." The Examiner additionally stated, "Further, the specification, which specifies the generic terminology should include, published product information sufficient to show that the generic terminology or the generic description are inherent in the article referred by the trademarks."

The Examiner's statement that published product information should be included in the specification is inappropriate because it goes well beyond what is required according to the M.P.E.P. M.P.E.P. § 608.01(v) states,

> However, if the product to which the trademark refers is set forth in such language that its identity is clear, the examiners are authorized to permit the use of the trademark if it is distinguished from common descriptive nouns by capitalization. If the trademark has a fixed and definite meaning, it constitutes sufficient identification unless some physical or chemical characteristic of the article or material is involved in the invention. In that event, as also in those cases where the trademark has no fixed and definite meaning, identification by scientific or other explanatory language is necessary. (citations omitted)

Applicants respectfully submit that the specification as amended meets the guidelines of M.P.E.P. § 608.01(v). First, all trademarks used have been amended to appear in capital letters. Secondly, for all trademarks used, either the specification

contains "scientific or other explanatory language" to make clear what product is referred to by the trademarks, or the trademark has a fixed and definite meaning. For example, Applicants point out the following language from the specification: "the osteogenic material is packed into a cylindrical mold, air or gas-permeable tubing (e.g., silastic or TEFLON®/FEP)...." Specification at 10. From this, it is clear that TEFLON®/FEP is gas-permeable tubing.

Applicants additionally point out the following passage: "HYAFF® materials are described, for example, in U.S. Pat. Nos. 4,851,521; 4,965,353; and 5,202,431; and EP 0 216 453, all of which are hereby incorporated by reference in their entireties herein. The HYAFF® materials are esters of hyaluronic acid having one or a combination of ester moieties (e.g., benzyl, ethyl, propyl, pentyl, or larger molecules such as hydrocortisone or methyl prednisone), as well as various degrees of esterification (i.e., partial esters or complete esters). Partial esters of HYAFF® materials are designated by percent esterification ranging from 50-99 % (e.g., HYAFF-11P65® and HYAFF-11P80®), while complete esters are 100 % esters of hyaluronic acid (e.g., HYAFF-11®)." Specification at 15. This passage contains "scientific or other explanatory language" to make clear what product is referred to by the trademarks contained therein.

Finally, Applicants point out this passage: "A number of commercially available syringes may be suitable for use in the present invention, and for administration of the compositions of the present invention. For example, suitable syringes are available the CALASEPT® syringe [JS Dental Manufacturing, Ridgefield CT] comprises sterile calcium hydroxide paste in isotonic saline solution, in a non-aspirating or modified

aspirating cartridge syringe; HENKE-JECT® aspirating syringe and-HYPO® dental syringes/needles [Smith & Nephew MPL, Franklin Park, IL]; intraosseous needles from MPL, Inc., Chicago IL; and LUER-LOK® Syringes [Becton Dickinson, Franklin Lakes, NJ], may all be appropriate syringes for use in the present invention. Any syringe capable of holding and delivering an injectable rod and/or enabling extrusion with an obdurator is appropriate for use." Specification at 20. From this passage, it is clear that the trademarks refer to syringes/needles with characteristics as indicated in the text.

Applicants have reviewed the trademarks in the specification and believe that the amended specification is now in compliance with the rules regarding trademarks. Applicants respectfully request the withdrawal of the objection to trademarks and their use.

Conclusion

Applicants note that claim 92 was not specifically rejected for any reason in the Office Action. Applicants respectfully request clarification or an indication that this claim presents allowable subject matter in the next communication from the Examiner.

Furthermore, Applicants respectfully point out that the final action by the Examiner presented some new arguments as to the application of the art against Applicants' invention. It is respectfully submitted that the consideration of these remarks would allow Applicants to reply to the final rejections and place the application in condition for allowance.

In view of the foregoing remarks, Applicants submit that this claimed invention is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants therefore request the entry of this Amendment, the

Examiner's reconsideration and reexamination of the application, and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: February 2, 2009

By: Elizabeth Mathiesen

Elizabeth E. Mathiesen, Ph.D.
Reg. No. 54,696
(617) 452-1693